



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0523]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Applications for Food and Drug Administration Approval to Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs  
AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0646. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Applications for Food and Drug Administration Approval to Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs--(OMB Control Number 0910-0646)--Extension

In the Federal Register of July 28, 2009 (74 FR 37163), FDA published a final rule that required, under § 314.81(b)(2)(ii)(b) (21 CFR 314.81(b)(2)(ii)(b)), the holder of a new drug application (NDA) to notify the Agency if an authorized generic drug is marketed by clearly including this information in annual reports in an easily accessible place and by sending a copy of the relevant portion of the annual reports to a central contact point. We took this action as part of our implementation of the Food and Drug Administration Amendments Act (Public Law 110-85), which requires that FDA publish a list of all authorized generic drugs included in an annual report after January 1, 1999, and that the Agency update the list quarterly. We initially published this list on June 27, 2008, on the Internet and notified relevant Federal Agencies that the list was published, and we will continue to update it.

Based on the number of annual reports the Agency currently receives under § 314.81(b)(2) containing authorized generic drug information, we estimate that we will receive approximately 500 annual reports containing the required information on authorized generic drugs. Based on the number of sponsors that currently submit these annual reports, we estimate that approximately 70 sponsors will submit these 500 annual reports. We estimate that each sponsor will need approximately 30 minutes to include the required information on authorized generic drugs in each annual report.

We also estimate that we will receive authorized generic drug information on first marketed generics in approximately 20 annual reports from approximately 20 sponsors, and that each sponsor will need approximately 1 hour to include the required information in each annual report.

We also estimate that we will receive a copy of that portion of each annual report containing the authorized generic drug information for approximately 500 annual reports from approximately 70 sponsors, and that each sponsor will need approximately 3 minutes to submit a copy of that portion of each annual report containing the authorized generic drug information.

In the Federal Register of May 10, 2013 (78 FR 27404), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information is as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

21 CFR 314.81(b)(2)(ii)(b)	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submission of authorized generic drug information in each annual report.	70	7	490	0.50 (30 minutes)	245
Submission of authorized generic drug information on first marketed generics in an annual report.	20	1	20	1	20
Submission of a copy of that portion of each annual report containing authorized generic drug information.	70	7	490	0.05 (3 minutes)	25
Total					290

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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